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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,900	11/20/2003	Xue Mei Zhou	3528.1	3341

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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,900	ZHOU, XUE MEI	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Currently, claims 1-6 are pending in the instant application and under examination. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following office action contains new grounds of rejection, and accordingly is made NON-Final. The rejections presented below constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow or are included in the grounds for rejection. This action is NON-FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection made under 35 USC 101 in the previous office action is withdrawn in view of applicant's arguments directed to an array comprising probes where each probe on the array is one of each of the specific 25 mer sequences of SEQ ID NOS: 1-982,914.

4. The rejections made under 35 USC 102 and 103, at sections 9 and 12 of the previous office action are withdrawn in view of the arguments made at page 11, first paragraph of the response where it is stated "Looking at just this one gene, there are 21 probes that are on the presently claimed array but not on the U74v2 array."

New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an array comprising a plurality of nucleic acid probes wherein each probe in the plurality of nucleic acid probes consists of one of the sequences listed in SEQ ID NOS 1-982,914 and wherein the plurality of nucleic acid probes of the array comprises each of the sequences listed in SEQ ID NOS 1-982,914, is not enabling for an array comprising a plurality of nucleic acid probes wherein each probe in the plurality of nucleic acid probes consists essentially of one of the sequences listed in SEQ ID NOS 1-982,914 and wherein the plurality of nucleic acid probes of the array comprises each of the sequences listed in SEQ ID NOS 1-982,914, or said array comprising each of the additional embodiments listed in claims 2-6. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention as broadly as it is claimed.

The claims are drawn to an array comprising a plurality of nucleic acid probes each probe in the plurality of nucleic acid probes consists essentially of one of the sequences listed in SEQ ID NOS 1-982,914 and wherein the plurality of nucleic acid probes of the array comprises each of the sequences listed in SEQ ID NOS 1-982,914. The claims further encompass an array comprising the complements of each SEQ ID NO:, as well as probes in which one of the sequences listed in SEQ ID NOS 1-982,914 has a mismatch at the central position.

The specification teaches that the sequences of SEQ ID NOS 1-982,914 correspond to regions of the mouse genome for at least 30,000 mouse genes (page 22). The claims recite probes

which "consists essentially" one of the sequences of SEQ ID NOS 1-982,914. As discussed in the MPEP at 2111.03, the term "consisting essentially of" is construed as "comprising" in the absence of clear indication in the specification or the claims as to what the "basic and novel characteristics" of the invention are. In the instant case, although the specification teaches that SEQ ID NOS 1-982,914 are 25 mer probes, the specification at page 18, teaches that the invention includes "longer nucleotides sequences which include the nucleic acid sequences listed in SEQ ID NOS 1-982,914 (page 18, lines 27-28). Accordingly, it is not clear if the basic and novel characteristics of the claimed invention are drawn to only the 25mer molecules of the recited SEQ ID NOS, or if it includes probes of longer, undefined length.

The specification asserts that the array can be used to measure gene expression (page 18), such as to determine the effects of a drug on gene expression (page 22). At page 17, the specification teaches that the array is preferably a single solid support so that expression levels of more than 30,000 mouse genes may be simultaneously analyzed in a single experiment using a single hybridization and a single chip. While the specification teaches an array that comprises a plurality of probes where each probe in the plurality consists of one of the sequences of SEQ ID NOS 1-982,914, the specification does not teach an array with longer probes which could be used to simultaneously analyze more than 30,000 mouse genes in a single experiment using a single hybridization. The response at page 6, asserts that the "applicant is claiming an array of 982,914 25 base probes to individually, reproducibly, and accurately interrogate the expression level of a collection of more than 30,000 mouse genes and to do so simultaneously". As noted above, however, the specification fails to clearly indicate the basic and novel characteristics of the invention, accordingly, the term has been broadly interpreted as "comprising". The

specification does not provide any guidance to arrive at an array with longer probes, which individually, reproducibly, and accurately interrogate the expression level of a collection of more than 30,000 mouse genes simultaneously. Applicants arguments at pages 6-9 of the response have been thoroughly reviewed but were found unpersuasive to overcome the rejection as the arguments are directed to an array where each probe consists of one of the sequences of each of SEQ ID NOS 1-982,914, whereas the claims, in light of the teachings of the specification, broadly encompass longer nucleic acid sequences comprising the indicated SEQ ID NOS. For example, at page 7, the response asserts that "Each probe sequence is selected because they met specified criteria that allow them to function together in a single assay... that is designed to hybridize specifically to a known or predicted mouse gene". However, it is known that differences in nucleic acid length and GC content, alter hybridization specificity. Therefore, while an array that comprises probes which each consist of one of the sequences of each of SEQ ID NOS 1-982,914 would be expected to have such properties, the specification does not teach the sequences from which the probes were made, nor does it provide guidance as to how to alter the specifically recited sequences to arrive at longer probes with the same hybridization and specificity properties. Accordingly, the limitations asserted in the response are not directed to the scope of the presently recited claims. As applicants arguments appear to interpret the claims as drawn to an array where each probe consists of each of one of the sequences of SEQ ID NOS 1-982,914, the rejection can be easily overcome by reciting "consists of" instead of "consists essentially of".

In the interest of compact prosecution, the following rejections are set forth.

Claim Rejections - 35 USC § 103

6. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unigene build 107 (June 2002) in view of Fodor et al (US Patent 6,309,822; 10/2001).

The claims are drawn to arrays comprising a plurality of probes wherein each probe "consists essentially of" one of SEQ ID NOS 1-982,914, wherein the plurality of probes of the array comprises each of SEQ ID NOS 1-982,914. As the specification does not clearly indicate the "basic and novel characteristics" of the claimed probes, the term "consists essentially of" has been broadly construed as equivalent to the term "comprising" (see MPEP 2111.03). Accordingly, the claims encompass an array which comprises at least 982,914 probes, wherein each probe "comprises" one of SEQ ID NOS 1-982,914. Claim 2 is further drawn to the array comprising at least one probe which is the complement of one of the sequences of claim 1. Claim 3 is further drawn to the array comprising at least one mismatch probe corresponding to one of the sequences of claim 1. Claim 4 is drawn to a solid support with the probes attached thereto. Claim 5 is further drawn to the array which comprises a plurality of beads, wherein the probes are attached to the beads and the probes on a bead consist essentially of one of the sequences listed in claim 1. Claim 6 is drawn to the support as a single contiguous solid support.

Unigene build 107 teaches the sequences of mouse genes and ESTs. Absent evidence to the contrary, the build listed above, is taken to provide the sequence information of SEQ ID NOS 1-982,914. The Unigene database does not teach probes comprising each of SEQ ID NOS 1-982,914, however Fodor teaches that there is a need to provide microfabricated arrays of large

numbers of oligonucleotide probes for gene expression analysis (col 2). Fodor teaches that the array can comprise up to 1,000,000 different oligonucleotide probes (col. 15, lines 15-20) in less than 1 cm^2, wherein sets of probes are chosen to be complementary over a gene sequence (col. 14; instant claim 6). Fodor teaches that the probes can range in size from 5 to 500 nucleotides (col. 3, lines 32-34). With regard to claims 2-3, Fodor teaches that the probes include normalization controls drawn to the complement of a probe designed from a particular target DNA sequence, as well as mismatch controls and normalization control probes (col. 22, lines 45-65). With regard to claims 4-5, Fodor teaches that the oligonucleotides in the array can be provided attached to beads (col. 21), including individual probes attached to each bead. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have constructed an array of probe sets, for genes and ESTs in the unigene database including probes which comprise the sequences of SEQ ID NOS 1-982,914, for the purpose of providing an array of probes for analysis of genes, including expression analysis as taught by Fodor. The ordinary artisan would have been motivated to provide an array of probe sets for murine sequences so as to be able to determine the presence of mouse target sequences because Fodor teaches that many disease states are characterized by differences in the expression level of various genes either through changes in the copy number of the genetic DNA or through changes in level of transcription.

Response to Arguments

7. The response traverses the rejection. The response asserts that the 982,914 probes selected for inclusion on the array are a unique set of probes that were carefully selected to

function as a set on an array for gene expression analysis and that the choice of probe sequence depends on numerous criteria. The response further asserts that not all sets of 982,914 twenty five bases probes from unigene build 107 would have been selected to have similar function. The response further asserts that "the specific claimed set of probes was chosen from the many possible sets of probes to obtain an array that has optimal performance given our current understanding of probe, array and assay performance." These arguments have been thoroughly reviewed but were not found persuasive. The claims are neither limited to only 982,914 probes, nor to probes which consist of each of the specifically recited SEQ ID NOS. Therefore the arguments that not all sets of 982,914 - 25 base probes from Unigene build 107 would have been selected to function as a set, or that numerous criteria were used to make the "specific claimed set" are not found persuasive as the claims are not so limited. Given the sequences of the mouse genome already known in the prior art and given the teachings of Fodor, it would have been prima facie obvious to the ordinary artisan at the time the invention was made to construct arrays of probes complementary to the mouse genome for the purpose of providing a tool for analysis of the presence of mouse target sequences. Although the prior art does not provide motivation to arrive at a set which includes probes which consist of the specific 25 mer sequences of each of SEQ ID NOS 1-982,914, the claims are not so limited.

8. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unigene build 74 in view of Fodor et al (US Patent 6,309,822; 10/2001).

The claims are drawn to arrays comprising a plurality of probes wherein each probe "consists essentially of" one of SEQ ID NOS 1-982,914, wherein the plurality of probes of the

array comprises each of SEQ ID NOS 1-982,914. As the specification does not clearly indicate the "basic and novel characteristics" of the claimed probes, the term "consists essentially of" has been broadly construed as equivalent to the term "comprising" (see MPEP 2111.03). Accordingly, the claims encompass an array which comprises at least 982,914 probes, wherein each probe "comprises" one of SEQ ID NOS 1-982,914. Claim 2 is further drawn to the array comprising at least one probe which is the complement of one of the sequences of claim 1. Claim 3 is further drawn to the array comprising at least one mismatch probe corresponding to one of the sequences of claim 1. Claim 4 is drawn to a solid support with the probes attached thereto. Claim 5 is further drawn to the array which comprises a plurality of beads, wherein the probes are attached to the beads and the probes on a bead consist essentially of one of the sequences listed in claim 1. Claim 6 is drawn to the support as a single contiguous solid support.

Unigene build 74 teaches the sequences of mouse genes and ESTs. Absent evidence to the contrary, the build listed above, is taken to provide the sequence information of SEQ ID NOS 1-982,914. The Unigene database does not teach probes comprising each of SEQ ID NOS 1-982,914, however Fodor teaches that there is a need to provide microfabricated arrays of large numbers of oligonucleotide probes for gene expression analysis (col 2). Fodor teaches that the array can comprise up to 1,000,000 different oligonucleotide probes (col. 15, lines 15-20) in less than 1 cm^2, wherein sets of probes are chosen to be complementary over a gene sequence (col. 14; instant claim 6). Fodor teaches that the probes can range in size from 5 to 500 nucleotides (col. 3, lines 32-34). With regard to claims 2-3, Fodor teaches that the probes include normalization controls drawn to the complement of a probe designed from a particular target DNA sequence, as well as mismatch controls and normalization control probes (col. 22, lines 45-

65). With regard to claims 4-5, Fodor teaches that the oligonucleotides in the array can be provided attached to beads (col. 21), including individual probes attached to each bead. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have constructed an array of probe sets, for genes and ESTs in the unigene database including probes which comprise the sequences of SEQ ID NOS 1-982,914, for the purpose of providing an array of probes for analysis of genes, including expression analysis as taught by Fodor. The ordinary artisan would have been motivated to provide an array of probe sets for murine sequences so as to be able to determine the presence of mouse target sequences because Fodor teaches that many disease states are characterized by differences in the expression level of various genes either through changes in the copy number of the genetic DNA or through changes in level of transcription.

Response to Arguments

9. The response traverses the rejection and argues "Unigene 74 contains at best a subset of the information contained in Unigene build 74" and that the combination of Unigene 74 and Fodor fails to make the claimed invention obvious for at least the same reasons. This argument has been thoroughly reviewed but was not found persuasive. Firstly, the statement that "Unigene 74 contains at best a subset of the information contained in Unigene build 74" is not understood. If it was applicants intention to state that build 74 is a subset of the information in build 107, such statements are further not persuasive as this does not address the fact that the ordinary artisan would be motivated to use the information in build 74 to arrive at an array of probes as set forth above in view of the teachings of Fodor. Any arguments made with regard to the

specific set of probes of SEQ ID NOS 1-982,914 is not found persuasive as the claims are not limited to probes which consist of these particular SEQ ID NOS as set forth above. Although the prior art does not provide motivation to arrive at a set which includes probes which consist of the specific 25 mer sequences of each of SEQ ID NOS 1-982,914, the claims are not so limited.

10. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall, (Science, vol. 296, May 10, 2002; page 1005) in view of Fodor et al (US Patent 6,309,822; 10/2001).

The claims are drawn to arrays comprising probes wherein each probe "consists essentially of" one of SEQ ID NOS 1-982,914, wherein the plurality of probes of the array comprises each of SEQ ID NOS 1-982,914. As the specification does not clearly indicate the "basic and novel characteristics" of the claimed probes, the term "consists essentially of" has been broadly construed as equivalent to the term "comprising" (see MPEP 2111.03). Accordingly, the claims encompass an array which comprises at least 982,914 probes, wherein each probe "comprises" one of SEQ ID NOS 1-982,914. Claim 2 is further drawn to the array comprising at least one probe which is the complement of one of the sequences of claim 1. Claim 3 is further drawn to the array comprising at least one mismatch probe corresponding to one of the sequences of claim 1. Claim 4 is drawn to a solid support with the probes attached thereto. Claim 5 is further drawn to the array which comprises a plurality of beads, wherein the probes are attached to the beads and the probes on a bead consist essentially of one of the sequences listed in claim 1. Claim 6 is drawn to the support as a single contiguous solid support.

Marshall teaches the completion of the draft of the sequence of the mouse genome. As the sequence information is taught to consist of 96% of the mouse genome, the PTO has basis for believing that it contains the sequence information of SEQ ID NOS 1-982,914. As stated in the MPEP in chapter 2100:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Marshall does not teach probes comprising each of SEQ ID NOS 1-982,914, however Fodor teaches that there is a need to provide microfabricated arrays of large numbers of oligonucleotide probes for gene expression analysis (col 2). Fodor teaches that the array can comprise up to 1,000,000 different oligonucleotide probes (col. 15, lines 15-20) in less than 1 cm^2, wherein sets of probes are chosen to be complementary over a gene sequence (col. 14; instant claim 6). Fodor teaches that the probes can range in size from 5 to 500 nucleotides (col. 3, lines 32-34). With regard to claims 2-3, Fodor teaches that the probes include normalization controls drawn to the complement of a probe designed from a particular target DNA sequence, as well as mismatch controls and normalization control probes (col. 22, lines 45-65). With regard to claims 4-5, Fodor teaches that the oligonucleotides in the array can be provided attached to beads (col. 21), including individual probes attached to each bead. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have constructed an array of probe sets, for genes and ESTs in the unigene database including probes which comprise the sequences of SEQ ID NOS 1-982,914, for the purpose of providing

an array of probes for analysis of genes, including expression analysis as taught by Fodor. The ordinary artisan would have been motivated to provide an array of probe sets for murine sequences so as to be able to determine the presence of mouse target sequences because Fodor teaches that many disease states are characterized by differences in the expression level of various genes either through changes in the copy number of the genetic DNA or through changes in level of transcription.

Response to Arguments

11. The response asserts that a database as taught by Marshall that contains 96% of the complete mouse genome contains more sequence information but less annotation information about which regions of the genome contain genes and that it would be even less likely that one of skill in the art would identify a set of probes that are equivalent in function to the claimed set of probes by combining Marshall with Fodor. This argument has been thoroughly reviewed but was not found persuasive as the claims do not set forth any particular function, nor are the claims limited to the array where each probe consists of only the SEQ ID NOS recited. Although the prior art does not provide motivation to arrive at a set which includes probes which consist of the specific 25 mer sequences of each of SEQ ID NOS 1-982,914, the claims are not so limited.

12. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall II, (Marshall, Science, vol. 292, May 4, 2001; page 822) in view of Fodor et al (US Patent 6,309,822; 10/2001).

The claims are drawn to arrays comprising a plurality of probes wherein each probe "consists essentially of" one of SEQ ID NOS 1-982,914, wherein the plurality of probes of the

array comprises each of SEQ ID NOS 1-982,914. As the specification does not clearly indicate the "basic and novel characteristics" of the claimed probes, the term "consists essentially of" has been broadly construed as equivalent to the term "comprising" (see MPEP 2111.03). Accordingly, the claims encompass an array which comprises at least 982,914 probes, wherein each probe "comprises" one of SEQ ID NOS 1-982,914. Claim 2 is further drawn to the array comprising at least one probe which is the complement of one of the sequences of claim 1. Claim 3 is further drawn to the array comprising at least one mismatch probe corresponding to one of the sequences of claim 1. Claim 4 is drawn to a solid support with the probes attached thereto. Claim 5 is further drawn to the array which comprises a plurality of beads, wherein the probes are attached to the beads and the probes on a bead consist essentially of one of the sequences listed in claim 1. Claim 6 is drawn to the support as a single contiguous solid support.

Marshall II teaches the completion of the draft of the sequence of the mouse genome. As the sequence information is taught to consist of the mouse genome, the PTO has basis for believing that it contains the sequence information of SEQ ID NOS 1-982,914. As stated in the MPEP in chapter 2100:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Marshall II does not teach probes comprising each of SEQ ID NOS 1-982,914, however Fodor teaches that there is a need to provide microfabricated arrays of large numbers of oligonucleotide probes for gene expression analysis (col 2). Fodor teaches that the array can

comprise up to 1,000,000 different oligonucleotide probes (col. 15, lines 15-20) in less than 1 cm^2, wherein sets of probes are chosen to be complementary over a gene sequence (col. 14; instant claim 6). Fodor teaches that the probes can range in size from 5 to 500 nucleotides (col. 3, lines 32-34). With regard to claims 2-3, Fodor teaches that the probes include normalization controls drawn to the complement of a probe designed from a particular target DNA sequence, as well as mismatch controls and normalization control probes (col. 22, lines 45-65). With regard to claims 4-5, Fodor teaches that the oligonucleotides in the array can be provided attached to beads (col. 21), including individual probes attached to each bead. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have constructed an array of probe sets, for genes and ESTs in the unigene database including probes which comprise the sequences of SEQ ID NOS 1-982,914, for the purpose of providing an array of probes for analysis of genes, including expression analysis as taught by Fodor. The ordinary artisan would have been motivated to provide an array of probe sets for murine sequences so as to be able to determine the presence of mouse target sequences because Fodor teaches that many disease states are characterized by differences in the expression level of various genes either through changes in the copy number of the genetic DNA or through changes in level of transcription.

Response to Arguments

13. The response asserts that the citation does not teach any sequence and there is no indication that the Celera database, available to subscribers, contained information about which regions of the genome were expressed and which were not. The response asserts that for the same reasons as why the claims are not obvious over Unigene 107 in view of Fodor et al., the

claims are also not obvious over a non annotated and incomplete genome database in view of Fodor. This argument has been thoroughly reviewed but was not found persuasive for the reasons already made of record in the response to arguments with regard the Unigene build 107 in view of Fodor. With regard to arguments pertaining to the Celera database, the claims are not limited to probes consisting of the SEQ ID NOS recited.

Maintained Rejections

Claim Rejections - 35 USC § 112

14. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended and are drawn to an array comprising a plurality of nucleic acid probes wherein the array "consists essentially of" each of the sequences listed in SEQ ID NOS 1-982,914. The claims are further drawn to an array comprising the complements of each SEQ ID NO:, as well as probes in which one of the sequences listed in SEQ ID NOS 1-982,914 has a mismatch at the central position.

The specification teaches that the sequences of SEQ ID NOS 1-982,914 correspond to regions of the mouse genome for at least 30,000 mouse genes (page 17). The claims recite probes "consisting essentially" one of the sequences of SEQ ID NOS 1-982,914. As discussed in the MPEP at 2111.03, the term "consisting essentially of" is construed as "comprising" in the

absence of clear indication in the specification or the claims as to what the "basic and novel characteristics" of the invention are. In the instant case, although the specification teaches that SEQ ID NOS 1-982,914 are 25 mer probes, the specification at page 18, teaches that the invention includes "longer nucleotides sequences which include the nucleic acid sequences listed in SEQ ID NOS 1-982,914 (page 18, lines 27-28). Although at page 9 of the response, applicant's argue that "the more limited scope transitional phrase 'consists essentially of' with reference to the composition of the nucleic acid probes of the array. The full length probes are no longer than 25 bases in length... they may be attached to the array via a linker molecule", the specification does not clearly indicate that the "basic and novel characteristics" are limited to probes which are only 25 bases in length. Accordingly, the recitation of "consisting essentially of", in light of the specification, is not limited as argued, but encompass an extremely large genus of full length genes, cDNAs, and variants, which need only minimally comprise the recited 25 mers, which have not been taught by the specification. The specification at page 32, states that the pool of unique sequences are complementary to approximately 36,000 full length mouse genes and EST clusters from Unigene database build 107. Such disclosure, however, does not provide for any fixed sequences comprising the claimed SEQ ID NOS as the information in database can be changed.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of an array comprising nucleic acid probes each probe consisting of one of SEQ ID NOS: 1-982,914 the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jehanne Sitton

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11/13/06